Advanced Computer Aided Gait Analysis (CAGA) with Comparison, Barefoot to Shod Intervention of a Diabetic Cohort; Preliminary Results of a Long Term Prospective IRB Diabetic Ulcer Reduction Study (DURS) Clinical Trial

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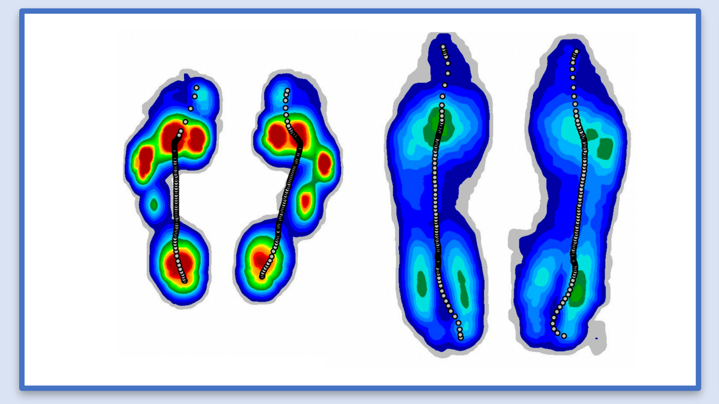
STATEMENT OF PURPOSE

Biomechanical and structural deformities create conditions that directly impact areas of identifiable risks on the plantar foot of the diabetic. This is secondary to multifactorial diabetic co-morbidities including both sensory and motor neuropathy. Hence, as a sequela of the neuropathy and deformities, this patient population will demonstrate an abnormal walking pattern, including diabetics exhibiting a less stable gait, truncated center of pressure and develop multiple abnormal temperospatial parameters in the stance phase of gait. These in turn create altered gait kinematics and increased peak plantar pressures which overall impair the ability to heal. Herein, a three dimensional foot of limited mass is colliding with a two dimensional mostly unyielding surface of relatively unlimited mass. It is estimated that 19-34% of patients with diabetes are likely to be affected with a diabetic foot ulceration in their lifetime. 85% of diabetic associated ulcerations are preceded by the development of foot ulcerations. Worldwide, even when a diabetic ulceration is finally healed, the stated risk of reoccurrence falls between 30% and 40% within the first 12 months. Utilizing CAGA (Computer Aided Gait Analysis) technology, the understanding of diabetic gait and the identification of occult high plantar foot pressures is possible, even prior to any apparent clinical signs or symptoms identified by patient and physician. CAGA enables focused evaluation of custom orthotic efficacy, with ulcer reduction and limb preservation.

METHODOLODOGY & PROCEDURES

Diabetic patients who have undergone conservative and/or surgical intervention and have healed diabetic foot ulcerations were entered into the CAGA DURS study since February 2021. All patients are informed and consented for participation within the IRB reviewed study. All participants receive a physical therapy evaluation. Participants are then walked on a treadmill outfitted with temporal-spatial pressure sensing technology, identifying 255 discrete parameters, static and dynamic, per foot. Baseline data is created through initial barefoot analysis. A 3-D foot scan is taken bilaterally and after CAGA review by the DURS IRB committee, an orthotic prescription is written. The custom orthotic is paired with a specific pair of diabetic shoes from a single manufacturer and is herein described as the "Solution." The patient is retested barefoot against their solution (orthotic+shoe), and the results are reviewed by the DURS IRB committee. Changes are made accordingly to obtain the best results. Participants are followed at regular intervals to reassure their solution is performing at its maximum potential.

Pressure Prints from select completed subjects to date (initial barefoot vs most recent solution (orthotic+shoe):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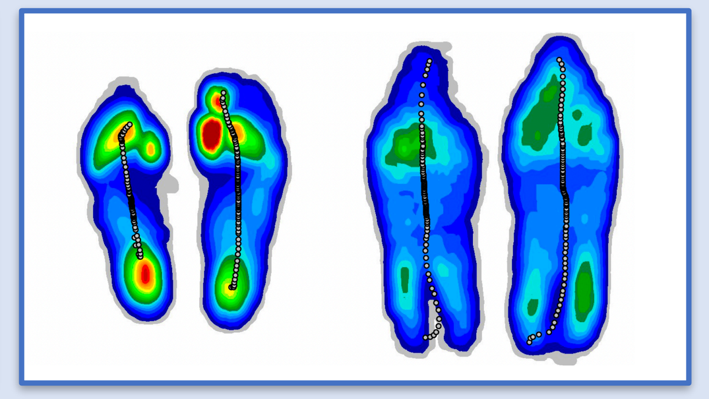
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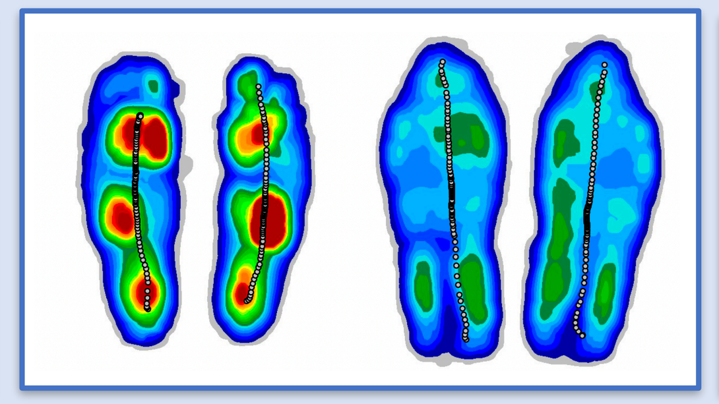
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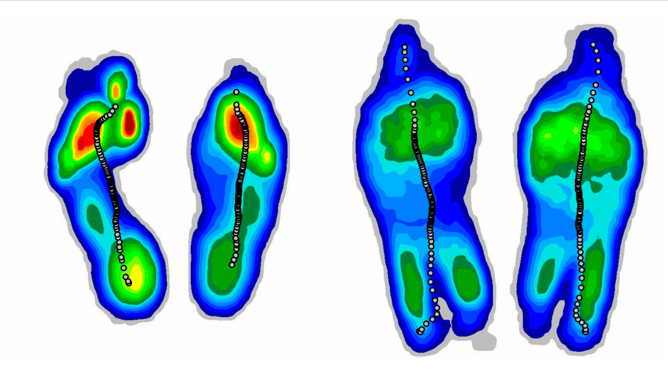
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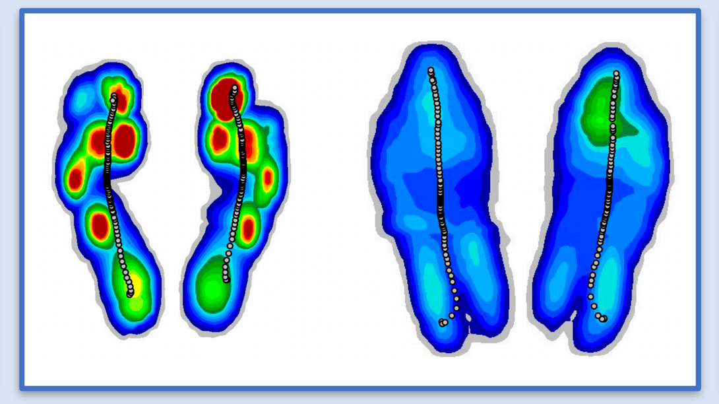
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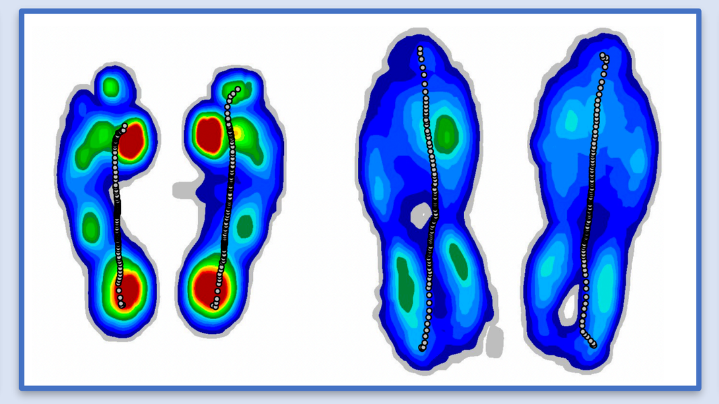
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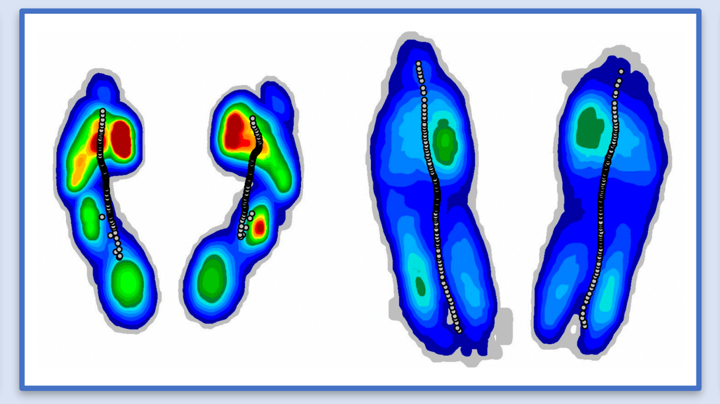
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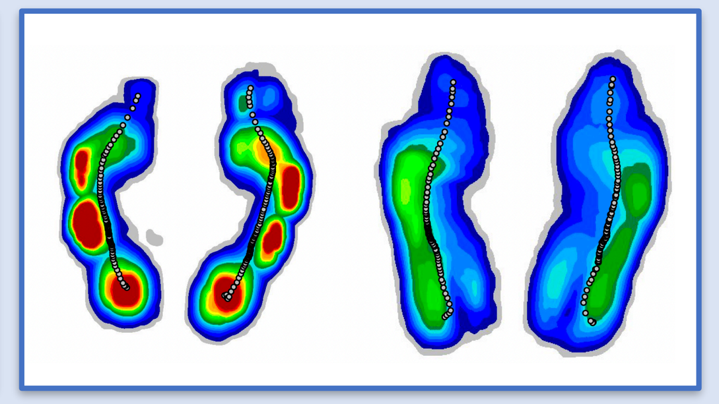
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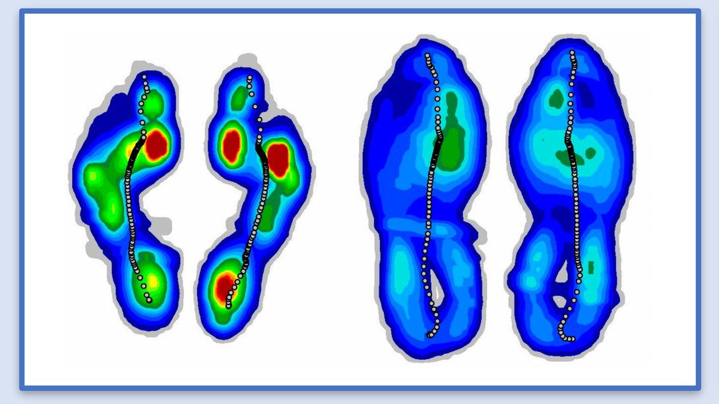
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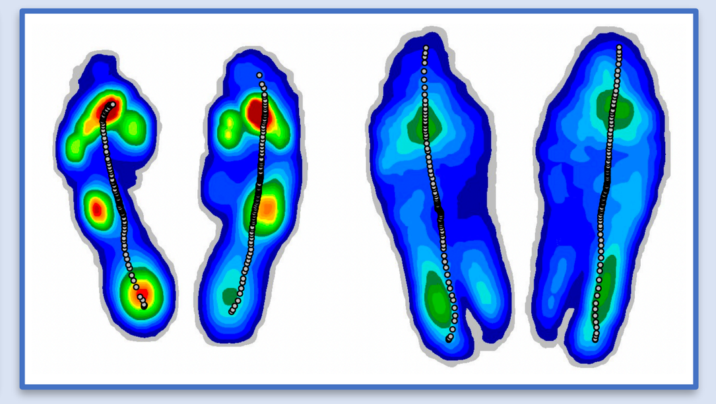
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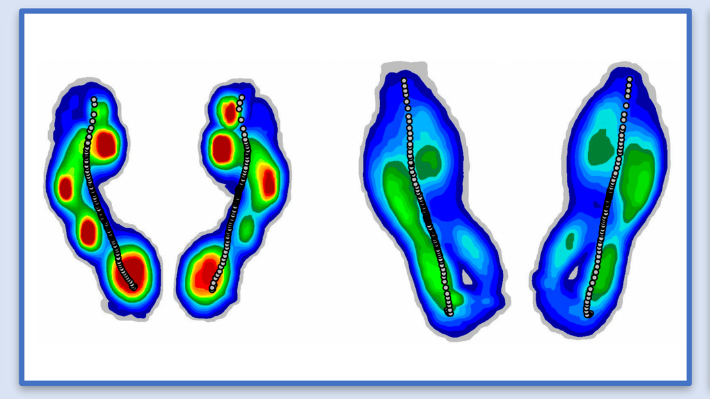
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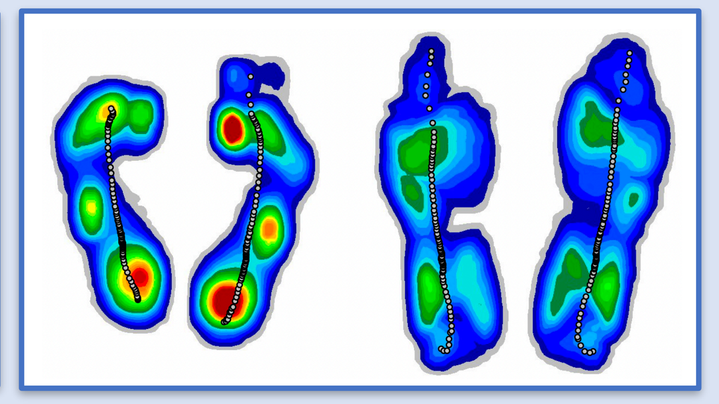
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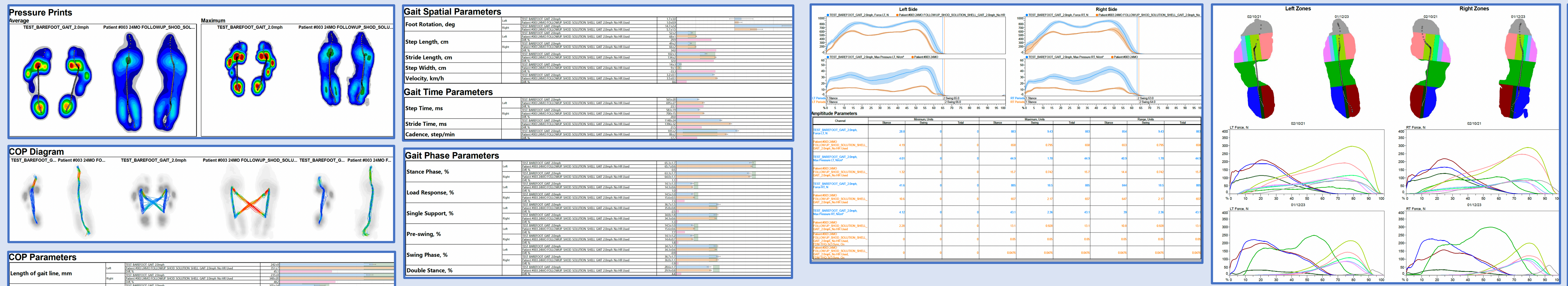
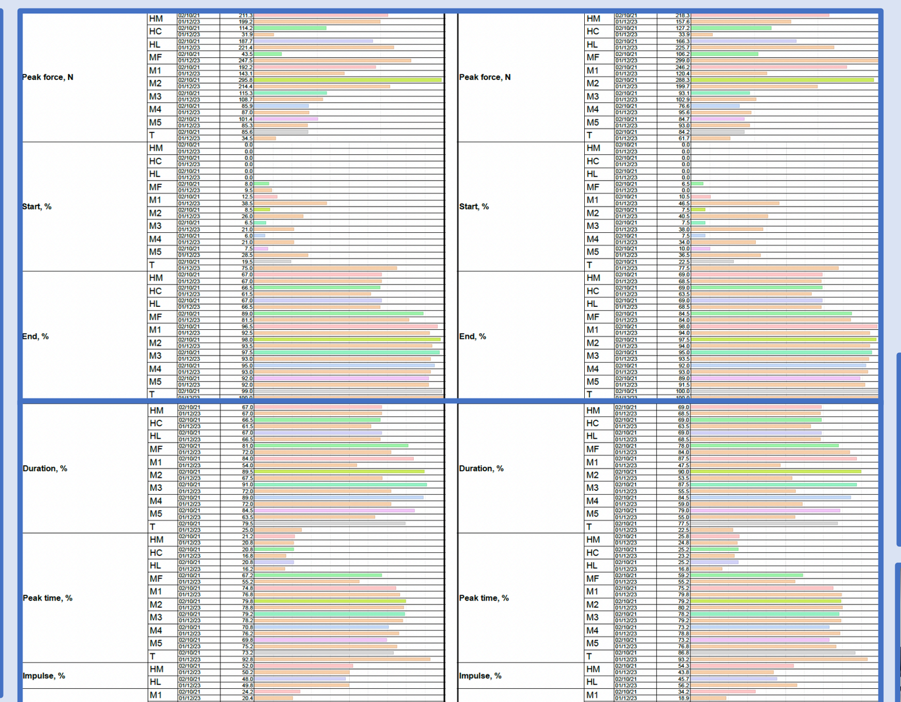
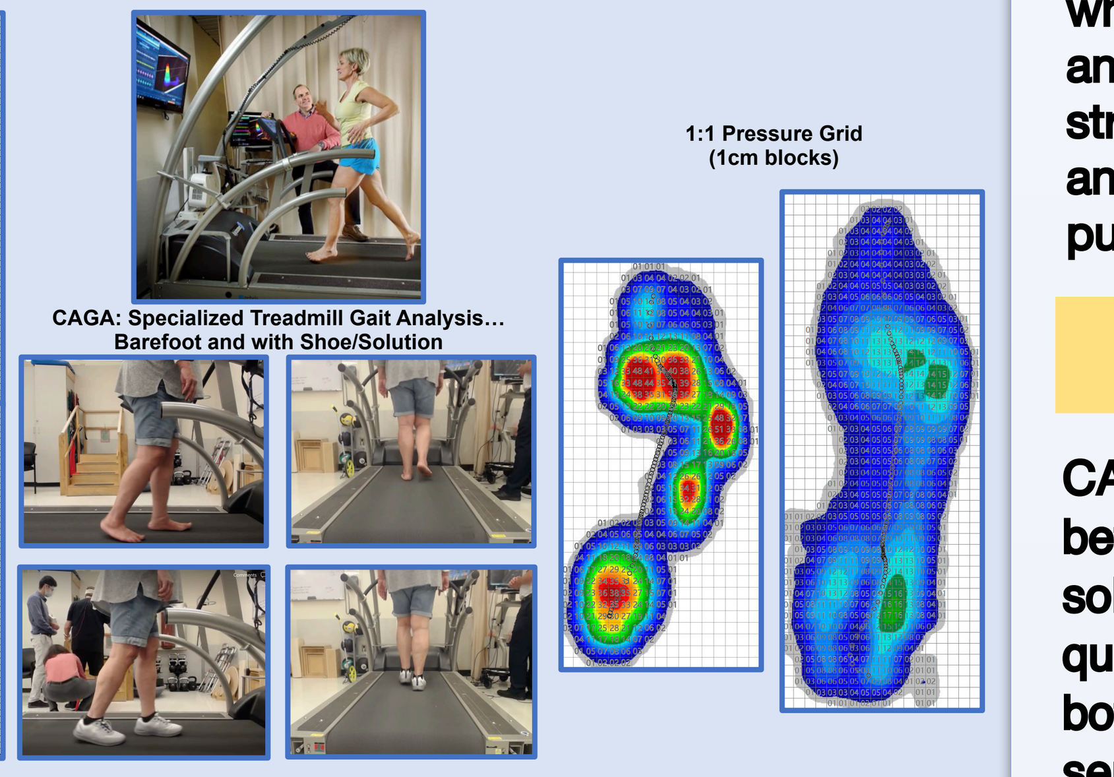
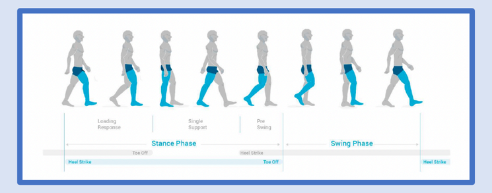
CAGA (Computer Aided Gait Analysis) DURS (Diabetic Ulcer Reduction Study) Process

Complete Computer Aided Gait Analysis (CAGA) Report (Subject #3)







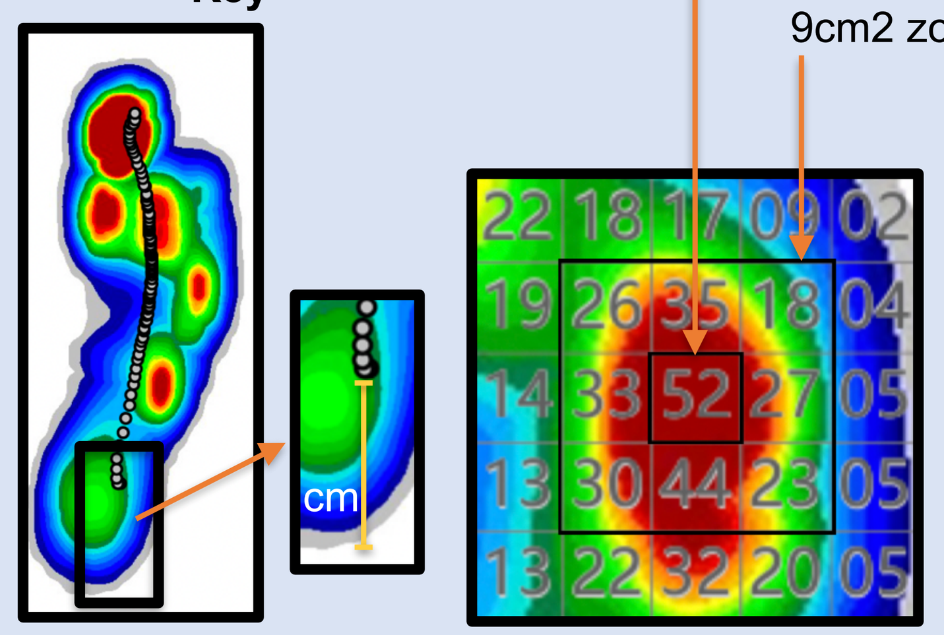


Initial Point of Contact of Center of Pressure Line Key

Pressure Point Key

Maximum pressure noted at 1cm2 zone

9cm2 zone



Left Foot: Initial Contact Point of Center of Pressure Line

Participant Number	Subject Number	Barefoot (in cm)	With Solution (in cm)	Difference (Between Barefoot and Solution, (cm)	% Change
1	3	4.50	3.20	1.30	28.89
4	4	5.00	3.70	1.30	26.00
5	7	7.90	6.00	1.90	24.05
8	9	8.80	8.10	0.70	7.95
10	11	8.80	2.80	6.00	68.18
12	12	5.60	6.20	-0.60	-10.71
13	13	4.80	3.30	1.50	31.25
14	14	5.70	3.40	2.30	40.35
15	15	5.70	2.80	2.90	50.88
16	16	4.80	3.80	1.00	20.83
17	20	4.50	2.70	1.80	40.00
21	21	13.20	4.70	8.50	64.39
22	22	10.70	5.20	5.50	51.40
23	23	4.40	3.90	0.50	11.36
24	25	4.60	3.40	1.20	26.09
26	26	6.10	3.50	2.60	42.62
27	27	4.80	3.60	1.20	25.00
28	29	12.30	3.90	8.40	68.29
30	30	9.70	3.70	6.00	61.86
31	33	5.60	5.00	0.60	10.71
34	34	7.70	7.10	0.60	7.79
35	37	22.80	10.80	12.00	52.63
38	39	3.70	5.00	-1.30	-35.14
40	40	4.30	3.40	0.90	20.93
41	41	5.60	4.70	0.90	16.07
42	42	3.80	2.90	0.90	23.68
43	43	8.80	5.40	3.40	38.64
AVERAGE				2.67	30.15

Right Foot: Initial Contact Point of Center of Pressure Line

Participant Number	Subject Number	Barefoot (in cm)	With Solution (in cm)	Difference (Between Barefoot and Solution, (cm)	% Change
1	3	4.30	2.90	1.40	32.56
4	4	4.80	4.70	0.10	2.08
5	7	25.00	18.40	6.60	26.40
8	9	10.70	5.80	4.90	45.79
10	11	6.20	3.20	3.00	48.39
12	12	5.10	6.80	-1.70	-33.33
13	13	5.30	3.60	1.70	32.08
14	14	7.50	3.20	4.30	57.33
15	15	7.20	3.20	4.00	55.56
16	16	4.20	4.00	0.20	4.76
17	20	4.50	3.20	1.30	28.89
21	21	21.50	16.00	5.50	25.58
22	22	16.00	4.80	11.20	70.00
23	23	4.90	3.00	1.90	38.78
24	25	4.30	3.80	0.50	11.63
26	26	6.60	3.20	3.40	51.52
27	27	4.80	2.90	1.90	39.58
28	29	6.40	3.30	3.10	48.44
30	30	4.20	2.70	1.50	35.71
31	33	6.20	5.20	1.00	16.13
34	34	4.30	4.80	-0.50	-11.63
35	37	21.30	15.30	6.00	28.17
38	39	3.20	3.20	0.00	0.00
40	40	4.20	3.50	0.70	16.67
41	41	5.30	4.30	1.00	18.87
42	42	3.50	2.80	0.70	20.00
43	43	6.70	5.00	1.70	25.37
AVERAGE				2.42	27.23

Left Foot: Plantar Pressure Comparisons

		LEFT	LEFT- Barefoot	LEFT -Solution	LEFT- Barefoot	LEFT- Solution		
Participant Number	Subject Number	Location of Maximum Pressure Recorded on Initial Barefoot Gait Study	Maximum Plantar Pressure noted at 1 cm2 zone (N/cm2)	Plantar Pressure noted at the same 1 cm2 zone (N/cm2)	Average Plantar Pressure noted at the 9 cm2 zone overlying the Maximum Plantar Pressure location (N/cm2)	Average Plantar Pressure noted at the same 9 cm2 zone (N/cm2)	Difference 1 cm2 zone (% reduction in pressure) (Barefoot vs. Solution) (N/cm2)	Difference 9 cm2 zone (% reduction in pressure) (Barefoot vs. Solution). (N/cm2)
1	3	Sub metatarsal 3	48	17	46.11	16.00	64.58	65.30
2	4	Sub metatarsal 1	65	14	50.11	13.44	78.46	73.17
3	7	Cuboid	25	13	30.11	10.11	48.00	66.42
4	9	Calcaneus	32	2	34.33	3.67	93.75	89.32
5	11	Calcaneus	48	4	30.11	5.78	91.67	80.81
6	12	Calcaneus	44	5	22.89	5.56	88.64	75.73
7	13	Sub metatarsal 1	82	17	41.56	15.78	79.27	62.03
8	14	Sub metatarsal 1	38	18	28.78	17.11	52.63	40.54
9	15	Sub metatarsal 1	87	9	42.44	7.78	89.66	81.68
10	16	Sub metatarsal 1	74	18	48.78	16.33	75.68	66.51
11	20	Calcaneus	53	7	48.11	9.33	86.79	80.60
12	21	Calcaneus	40	6	24.00	7.00	85.00	70.83
13	22	Sub metatarsal 1	45	18	51.67	16.33	60.00	68.39
14	23	Sub metatarsal 1	63	16	86.44	14.00	74.60	83.80
15	25	Sub metatarsal 4	93	23	48.56	21.22	75.27	56.29
16	26	Cuboid	58	22	61.78	17.89	62.07	71.04
17	27	Sub metatarsal 1	69	16	38.67	15.56	76.81	59.77
18	29	Sub metatarsal 1	34	13	27.56	12.22	61.76	55.65
19	30	Sub metatarsal 3	17	12	18.67	12.78	29.41	31.55
20	33	Calcaneus	35	4	27.78	5.56	88.57	80.00
21	34	Sub metatarsal 1	24	12	26.78	11.00	50.00	58.92
22	37	Sub metatarsal 3	22	9	19.78	8.56	59.09	56.74
23	39	Calcaneus	36	14	35.00	13.00	61.11	62.86
24	40	Sub metatarsal 3	57	17	35.33	15.89	70.18	55.03
25	41	Cuboid	62	18	39.22	16.33	70.97	58.36
26	42	Calcaneus	49	10	32.00	11.33	79.59	64.58
27	43	Cuboid	38	12	27.11	11.33	68.42	58.20
		AVERAGE	47.79	12.36	36.56	11.82	71.18	65.71

Right Foot: Plantar Pressure Comparisons

		RIGHT	RIGHT- Barefoot	RIGHT- Solution	RIGHT- Barefoot	RIGHT- Solution		
Participant Number	Subject Number	Location of Maximum Pressure Recorded on Initial Barefoot Gait Study	Maximum Plantar Pressure noted at 1 cm2 zone (N/cm2)	Plantar Pressure noted at the same 1 cm2 zone (N/cm2)	Average Plantar Pressure noted at the 9 cm2 zone overlying the Maximum Plantar Pressure location (N/cm2)	Average Plantar Pressure noted at the same 9 cm2 zone (N/cm2)	Difference 1 cm2 zone (% reduction in pressure) (Barefoot vs. Solution) (N/cm2)	Difference 9 cm2 zone (% reduction in pressure) (Barefoot vs. Solution). (N/cm2)
1	3	Sub metatarsal 1	48	15	39.33	13.33	68.75	66.10
2	4	Sub metatarsal 1	65	6	47.89	7.11	90.77	85.15
3	7	Calcaneus	25	5	20.89	5.00	80.00	76.06
4	9	Sub metatarsal 3	32	11	29.56	11.67	65.63	60.53
5	11	Sub metatarsal 1	48	16	38.33	15.11	66.67	60.58
6	12	Sub metatarsal 4	44	15	34.00	13.56	65.91	60.13
7	13	Cuboid	82	12	66.44	12.00	85.37	81.94
8	14	Sub metatarsal 3	38	24	34.44	22.56	36.84	34.52
9	15	Hallux	87	16	69.44	13.78	81.61	80.16
10	16	Sub metatarsal 1	74	12	58.56	11.56	83.78	80.27
11	20	Calcaneus	53	8	45.67	10.89	84.91	76.16
12	21	Calcaneus	40	8	32.56	7.89	80.00	75.77
13	22	Sub metatarsal 1	45	16	34.44	15.11	64.44	56.13
14	23	Sub metatarsal 1	63	24	54.22	23.00	61.90	57.58
15	25	Cuboid	93	21	63.11	18.00	77.42	71.48
16	26	Sub metatarsal 5	58	18	41.22	14.44	68.97	64.96
17	27	Sub metatarsal 4	69	14	49.78	13.00	79.71	73.88
18	29	Base of the 5th metatarsal	34	12	30.11	9.67	64.71	67.90
19	30	Sub metatarsal 3	17	13	16.00	12.44	23.53	22.22
20	33	Sub metatarsal 3	35	25	34.44	24.11	28.57	30.00
21	34	Calcaneus	24	6	20.33	6.56	75.00	67.76
22	37	Base of the 5th metatarsal	22	10	18.44	9.44	54.55	48.80
23	39	Sub metatarsal 1	36	16	24.78	13.78	55.56	44.39
24	40	Sub metatarsal 3	57	17	40.67	16.22	70.18	60.11
25	41	Sub metatarsal 1	62	15	47.00	14.33	75.81	69.50
26	42	Calcaneus	49	14	41.56	14.56	71.43	64.97
27	43	Calcaneus	38	8	33.00	9.44	78.95	71.38
		AVERAGE	47.79	13.46	38.08	12.81	68.18	63.28

RESULTS

27 diabetic patients [Mean age 61 years- range 34-84, Male: 81%, White 67%, Black 30%, Hispanic 3%. DM Type 2: 93%, DM Type 1: 7%, Non-smoker: 67%, Former smoker: 33%], who met inclusion criteria were analyzed. CAGA identified peak plantar pressures representing areas at risk for diabetic foot ulceration. Within these areas of highest risk (Sub-metatarsal 1: 33%, Calcaneus: 24%, Sub-metatarsals 3,4: 20%, Cuboid: 13%,…), the maximum pressure recorded within a single square centimeter was identified and a comparison of this area pre- and post-"solution" was performed. This yielded an average 66.18% decrease in pressure (Left: 47.79nm2 vs. 12.36nm2 and Right: 47.79nm2 vs. 13.46nm2, p<0.001). It was also noted that the initial contact point of gait was decreased (moved more proximally/posteriorly by an average of a 28.69% (Left: 2.67cm and Right: 2.42cm, p<0.001), elongating the gait line, and subsequently dispersing the forces acting upon the foot. Six of the most consequential parameters which are contributory to this success are being statistically analyzed and include: length and deviation of gait line, stride length, lateral symmetry, step width, foot abduction, and stance vs. swing ratio. They will be fully analyzed and published once full cohort (n=90) is completed.

CONCLUSION

CAGA allows practitioners to perform a detailed comparison between a diabetic patient's gait while barefoot and with solution (orthotic and specific shoe) to obtain the best quantitative data. This objective data allows users to analyze both the biomechanical deformity (a result of both motor and sensory neuropathy) and structural deformity, as well as the effectiveness of footwear modification. As a highly accurate, objective diagnostic tool, CAGA yields the ability to capture temporospatial parameters, both statically and dynamically, pinpointing plantar regions that are at risk. These areas can be identified even before they show signs of pre-ulceration. It allows a detailed evaluation of the patients gait, identifying areas of concern, success in the management of problematic areas, and areas that need further attention. Our preliminary data has validated our ability to provide increasing gait stability and off-loading, therefore leading to a decrease chance of ulceration potential.

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